Remarks/Arguments

Reconsideration of this Application and entry of this Amendment is respectfully requested.

In the Office Action dated December 1, 2004, the Examiner stated that claims 1-27 are pending in the application. The instant application was filed with claims 1-31. Applicant respectfully requests that the Examiner provide Applicant with information indicating the status of claims 28-31.

ELECTION/RESTRICTIONS

The Office Action dated December 1, 2004 required restriction of the claims into four distinct species. In a telephone conversation with the Examiner on 11/18/2004, Attorney for Applicant Louis Cullman provisionally elected Species 1, namely claims 1-5, 7, 9-17, 19-23 and 25-27 without traverse. Applicant hereby affirms the election of Species 1, claims 1-5, 7, 9-17, 19-23 and 25-27 and withdraws claims 6, 8, 18 and 24 without prejudice to filing in continuation or divisional applications.

CLAIM REJECTIONS UNDER 35 USC 112

Claims 15-16 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states that claims 15 and 16 can be porous or non-porous and requests Applicant direct the interpretation of these claims to the specification and drawings for support and description. Additionally claim 27 depends from itself.

Applicant has amended claims 15 and 16 to contain the language "manufactured from a _____material" to distinctly claim the subject matter which Applicant regards as the invention, namely that the apparatus is formed of material which can be porous (claim 15) or non-porous (claim 16). Support for this amendment is found in the specification on page 6, paragraph 26 line 5. The amendments to claims 15-16 do not add any new matter.

Applicant has amended claim 27 to properly depend from claim 26. Additionally, claim 27 was amended to correct several typographical errors. The amendments to claim 27 do not add any new matter.

While no objections were raised to claim 12, during the preparation of this response typographical errors were found in claim 12 and these errors were corrected in amended claim 12. The amendments to claim 12 do not add any new matter.

CLAIM REJECTIONS UNDER 35 USC 102

Claim 1-5, 7, 9-17, 19-23 and 25-27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al. (5,968,091). According to MPEP 2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently disclosed, in a single prior art reference." Therefore Applicant will now address each of the Examiner's rejections individually.

1. "Referring to figure 7, Pinchuk et al teaches a modular stent comprising: A first stent module (a first plurality of zig-zags 34) defining a first passageway; at least a second stent module (a second plurality of zig-zags 36 adjacent to the first) defining a second passageway; and At least one polymer bridge in communication with the first and second module. See at least figure 7 and column 3, lines 20 et seq. Teaching a polymeric coating and types of polymers over most of the stent including internal and external surfaces." (See December 1, 2004 Office Action at page 4 line 30 to page 5 line 6)

Applicant respectfully asserts that the language the Examiner uses to describe the Pinchuk stent, "a first plurality of zig-zags 34" and "a second plurality of zig-zags 36" is not used in the Pinchuk patent and does not describe the Pinchuk stent. The Wiktor-type stent described in the Pinchuk patent and cited by the Examiner is made from a single wire filament and therefore does not include a first plurality of zig-zags or a second plurality of zig-zags.

Pinchuk discloses polymer coatings from prior art stents including wire mesh stents and Wiktor-type stents. The Wiktor-type stent disclosed in Pinchuk is a single

strand of zig-zag filament which is helically wrapped around a mandrel. The Wiktor-type stent is fully described in column 2 line 55 through column 3 line 2 of the Pinchuk patent as follows: "A Wiktor-type stent 30 is shown in prior art FIG. 4 in conjunction with a balloon catheter 31. The stent 30 is made of a single strand of zig-zag filament 32 which is helically wrapped around a mandrel. While the filament 32 does not necessarily cross over itself, adjacent zig-zags touch each other or come close to touching each other. One of the disadvantages of the Wiktor-type stent is that the zig-zag wire tends to expand non-uniformly when expanded in an artery by a balloon catheter. In addition, the non-braided stent can unfurl during maneuvering the balloon catheter in the vasculature, which can cause placement problems as well as damage to the endothelium. In addition, the hoop strength of the Wiktor-type stent is relatively low." Pinchuk provides a stent with increased hoop strength, that resists tapering and maintains flaring, exhibits little or no abrasion of wires in the vasculature and maintains a substantially constant diameter in the vessel by coating a conventional stent (including the Wiktor-type stent) with a polymer such that the polymeric coating binds the crossover points of the wires, or, in the case of a Wiktor-type stent, binds adjacent zig-zags of wires without occluding the interstices of the stent lattice (column 3 lines 9-27)

The problems with the Wiktor-type stent that Pinchuk addresses are not issues with the stent used in the instant application. Applicant's stent is comprised of stent modules that are joined together by the polymer coating. As disclosed in paragraph 0026 of the instant application, the radially expandable modular stent comprises at least two stent modules joined by at least one polymer bridge. Additionally, paragraph 0029 in the description of FIG. 3 discloses a second end of one stent module coupled to the first end of a second stent module by coating with polymer material. The stent modules may be coated with a polymer thereby forming a polymer bridge between the two stent modules. Modular stents are known in the art to provide improved flexibility over Wiktor-type stents due to their modular design. Applicant's stent does not have the problems listed for the Wiktor-type stent above. Pinchuk teaches coating stents for enhancement of stent hoop strength, not for lateral and longitudinal flexibility. Therefore independent claims 1, 17, 19 and 28 have been amended to add the language "having

improved lateral and longitudinal flexibility" to the preamble and the limitation "such that lateral and longitudinal flexibility is improved." Support for these amendments can be found in paragraph 0029. No new matter was added as a result of the amendments to claims 1, 17, 19 and 28.

Therefore, because each and every element as set forth in the claims, namely "A radially expandable modular stent having improved lateral and longitudinal flexibility for implantation within the body of a patient, comprising: a first stent module defining a first passageway; at least a second stent module defining at least a second passageway; and a least one polymer bridge in communication with said first stent module and at least said second stent module, said polymer bridge coupling said first stent module to at least said second stent module such that lateral and longitudinal stability is improved, wherein said first passageway and said at least said second passageway are in fluid communication," was not found, either expressly or inherently, in the Pinchuk patent, the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

The polymer coating of the instant application is an integral part of the manufacture of this novel stent, rather than an attempt at improving functionality in an existing stent. Additionally, as the modular stent is not anticipated by Pinchuk et al, this point of rejection is moot and the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

2. "Regarding at least claim 7 requiring a polymer hinge defining a gap, see column 2, lines 60-63, teaching the modules can touch or not touch (producing a gap)." (See December 1, 2004 Office Action at page 5 line 7-8)

One feature of the stent of the instant application is the flexible hinge or gap that is formed between the second end of one stent module and the first end of a second stent module thereby permitting movement of the stent modules relative to each other and enhancing the lateral and longitudinal flexibility of the stent (paragraph 0029). The specification of the Pinchuk patent does not teach a stent in which stent modules are joined by a polymer bridge, thereby permitting movement of the stent modules relative

to each other. Additionally since Pinchuk *does not teach a modular stent*, this point of rejection is moot and at least claim 7 of the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

3. "Regarding the therapeutic agent, see column 4, lines 18 et seq." (See December 1, 2004 Office Action at page 5 line 9)

Additionally since Pinchuk *does not teach a modular stent*, this point of rejection is moot and the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

4. "Regarding at least claim 13, see column 4, lines 28 et seq. (See December 1, 2004 Office Action at page 5 line 10)

Claim 13 states that the polymer bridge contains at least one radio-opaque or echogenic material. Radio-opaque is defined as "not penetrable by x-rays or other forms of radiant energy" (Dorland's Illustrated Medical Dictionary). Echogenic is defined as "in ultrasonography, giving rise to reflections (echoes) of ultrasound waves" (Dorland's Illustrated Medical Dictionary). Pinchuk et al do not disclose or teach including a material with radio-opaque or echogenic properties in the polymer coating. Therefore at least claim 13 of the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

5. "Regarding claim 15, module is porous, the module configuration of both applicant and Pinchuk et al are similar utilizing a zig-zag configuration which leaves opening in the stent also known in the art as porous." (See December 1, 2004 Office Action at page 5 line 11-13)

The stents of the instant application can be manufactured from materials which are porous or non-porous and claim 15 has been amended as such. Support for this claim amendment can be found in paragraph 0026 of the specification. Therefore the Examiner's rejection is moot and claim 15 is not anticipated under 35 USC 102(b) by Pinchuk et al.

6. "Regarding claim 16, module is non-porous, the materials used to form the modules are non-porous." (See December 1, 2004 Office Action at page 5 line 14-15)

The stents of the instant application can be manufactured from materials which are porous or non-porous and claim 16 has been amended as such. Support for this claim amendment can be found in paragraph 0026 of the specification. Therefore the Examiner's rejection is moot and claim 16 is not anticipated under 35 USC 102(b) by Pinchuk et al.

7. "Regarding claim 25, see at least column 7, lines 60 et seq. (See December 1, 2004 Office Action at page 5 line 16)

Claim 25 has been cancelled, and therefore the Examiner's rejection is moot.

In conclusion, according to MPEP 2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently disclosed, in a single prior art reference." As Pinchuk does not teach a modular stent, Pinchuk does not teach the stent of the instant application and there the claims of the instant application are not anticipated under 35 USC 102(b) by Pinchuk et al..

The Examiner is respectfully requested to withdraw the rejections under 35 USC 102(b).

SPECIFICATION

The specification was objected to as failing to provide proper antecedent basis for the claim subject matter (37 CFR 1.75(d)(1) and MPEP § 608.01(o)). Correction of the following was requested: Claim 15-16 are not supported.

Applicant has amended claims 15 and 16 to include the language "manufactured from a _____ material" to more accurately define that which Applicant regards as porous (claim 15) or non-porous (claim 16). Therefore claims 15 and 16 are supported by the specification as filed.

Additionally, Applicant amended paragraph 0033 to correct a typographical error.

Conclusions

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

Dated: March 10, 2005

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